IFW

Attorney Docket No. TMIA-001/00U

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Noboru SHIMIZU

Confirmation No.: To Be Assigned

Application No.: 10/572,962

Group Art Unit: To Be Assigned

Filed: March 21, 2006

Examiner: To Be Assigned

For:

5-AMINOSALICYLIC ACID SOLID PREPARATION IMPROVED IN

DISCOLORATION AND METHOD OF STORING THE SAME

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop Amendment
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401 Dulany Street
Alexandria, VA 22314

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97(b)

In accordance with the duty of disclosure set forth in 37 C.F.R. §1.56, Applicant(s) hereby submits the following information in conformance with 37 C.F.R. §§1.97 and 1.98.

- [X] Pursuant to 37 C.F.R. §1.98, copies of documents 1-30 cited in the attached Form PTO-1449 are enclosed.
- [X] Documents 1, 2, 5-16 and 19 cited in the attached Form PTO-1449 are in a foreign language. An English abstract for document 1, published PCT patent application WO 81/02671 A1, may be found on the face page of the publication. English abstracts for documents 5 and 6 may be found on the face pages of documents 1 and 2, as these Japanese patent applications are national stage filings of published PCT patent applications WO 81/02671 A1 and WO 83/00479 A1 respectively. English abstracts for documents 7-16 are cited in the attached Form PTO-1449 as documents 21-30. An English translation of document 19 is cited in the attached Form PTO-1449 as document 20.

This Information Disclosure Statement is filed within any one of the following time periods:

[X] before the mailing date of a first office action on the merits; or

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It is respectfully requested that the Examiner consider the above-noted information and return an initialed copy of the attached Form PTO-1449 to the undersigned. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 50-1283.

Dated: May <u>19</u>, 2006

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Attorney Docket No. Application No. INFORMATION DISCLOSURE CITATION TMIA-001/00US 10/572,962 (Use several sheets if necessary) Applicants: Noboru SHIMIZU PAGE 1 of 1 MAY 1 9 2006 - W PTO Form 1449 Filing Date: March 21, 2006 Group Art Unit: To Be Assigned TATES TRANSPERIGN PATENT DOCUMENTS Document No. Date Class Sub-Class Country Translation WO 81/02671 A1 10/01/1981 **WIPO** 1. Abstract on face page 2. WO 83/00479 A1 02/17/1983 **WIPO** Abstract on face page 3. WO 01/85147 A2 11/15/2001 **WIPO** WO 03/032952 A1 04/24/2003 WIPO 4. 5. JP 57-500432 03/11/1982 Japan No No 6. JP 58-501171 07/21/1983 Japan 7. JP 3-47121 02/28/1991 Japan Abstract attached JP 3-47161 8. 02/28/1991 Japan Abstract attached 9. JP 8-38883 02/13/1996 Japan Abstract attached 10. JP 8-81360 03/26/1996 Japan Abstract attached 11. JP 10-15032 01/20/1998 Japan Abstract attached 12. JP 10-309427 11/24/1998 Japan Abstract attached 13. JP 2000-50849 02/22/2000 Japan Abstract attached 14. JP 2000-50850 02/22/2000 Japan Abstract attached 15. JP 2001-37457 02/13/2001 Japan Abstract attached 16. JP 2003-38143 02/12/2003 Japan Abstract attached OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.) Campieri et al., "Treatment of Ulcerative Colitis with High-Dose 5-Aminosalicylic Acid Enemas," The Lancet 2:270-271 (1981). Jensen et al., "Identification of major degradation products of 5-aminosalicylic acid formed in aqueous solutions and in pharmaceuticals," Int. J. Pharmaceutics 88:177-187 (1992). Iyakuhin Tenkabutsu Jiten, "Calcium Oxide;" "Magnesium Oxide," "L-Cystine," "Potassium Carbonate," "Calcium Carbonate," "L-Methionine," Magnesium Sulfate," "L-Cysteine," Sodium Thioglycollate," and "Sodium Thiomalate," pp. 59-60, 62, 80, 138, 148, 184-185, 198-199, Encyclopedia of Pharmaceutical Excipients, First Edition, Edited by Japan Pharmaceutical Excipients Council (1994). English Translation of Iyakuhin Tenkabutsu Jiten, "Calcium Oxide;" "Magnesium Oxide," "L-Cystine," "Potassium Carbonate," "Calcium Carbonate," "L-Methionine," Magnesium Sulfate," "L-Cysteine," Sodium Thioglycollate," and "Sodium Thiomalate," pp. 59-60, 62, 80, 138, 148, 184-185, 198-199, Encyclopedia of Pharmaceutical Excipients, First Edition, Edited by Japan Pharmaceutical Excipients Council (1994), 10 pages. 21. English language abstract of JP 3-47121, Patent Abstracts of Japan, Japan Patent Office, 2 pages (1991). Date Considered Examiner Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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28. English language abstract of JP 2000-50850, Patent Abstracts of Japan, Japan Patent Office, 1 page (2000).

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